GE Healthcare

ÄKTAready

Safety Instructions

ReadyToProcess

Important user information

All users must read this entire manual to fully understand the safe use of ÄKTAready.

Safety notices

This manual contains warnings and cautions concerning the safe use of the product. See definitions below.

WARNING! The WARNING symbol and notice highlight instructions that must be followed to avoid personal injury. Do not proceed until all stated conditions are clearly understood and met.

CAUTION! The CAUTION notice highlights instructions that must be followed to avoid damage to the product or other equipment. Do not proceed until all stated conditions are met and clearly understood.

Notes

Note: *A Note is used to indicate information that is important for trouble-free and optimal use of the product.*

Recycling

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of equipment.

WARNING! This is a Class A product. In a domestic environment, it might cause radio interference, in which case the user might be required to take appropriate measures.

WARNING! All repairs should be done by personnel authorized by GE Healthcare. Do not open any covers or replace parts unless specifically stated in instructions.

CE-certification

This product complies with the European directives listed below, by fulfilling corresponding harmonized standards. A copy of the Declaration of Conformity is available on request.

ÄKTAready complies with:

- MD 98/37/EC Machinery Directive
- EMC 2004/108/EC Electro Magnetic Compatibility
- LVD 2006/95/EC Low Voltage Directive.

Conformity

Applied harmonized standards:

- EN ISO 12100-1 Safety of machinery - Basic concepts, general principles for design, Part 1: Basic terminology, methodology
- EN ISO 12100-2 Safety of machinery - Basic concepts, general principles for design, Part 2: Technical principles
- EN 61010-1 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements
- EN 61326 Electrical equipment for measurement, control and laboratory use - EMC requirements for equipment intended for use in industrial location

The **CE** logo and corresponding declaration of conformity, is valid for the instrument when it is:

- used as a stand-alone unit, or
- connected to other CE-marked GE Healthcare instruments, or
- connected to other products recommended or described in this manual, and
- used in the same state as it was delivered from GE Healthcare except for alterations described in this manual.

This product meets the requirements of applicable European directives. A copy of the corresponding Declaration of Conformity is available upon request.

Note: *The Declaration of conformity is valid only for systems that are marked with the **CE** logo* **CE-certification**:

CE

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1 Safety instructions

This chapter contains the English version of the safety instructions for ÄKTAready .

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1.1 Introduction

About this handbook

The purpose of this handbook is to describe safety precautions, and emergency and disposal procedures for ÄKTAready™, as well as provide instructions for recycling. A presentation of safety labels is also included.

Note: All users must read the instructions in this chapter to fully understand the safe use of ÄKTAready.

Note: ÄKTAready and the UNICORN™ software should be installed and prepared by personnel authorized by GE Healthcare.

Note: To avoid risk of injury, operation and user maintenance should be performed by properly trained personnel only, and in accordance with the instructions in the documentation supplied.

This handbook does not contain user information, safety instructions, or specifications pertaining to the PC.

If you have any questions, or require further information, please contact your local GE Healthcare office or service department. Contact information is listed on the back cover of this handbook.

The ÄKTAready system

ÄKTAready is an isocratic, low pressure, automated liquid chromatography system using ready-to-use ÄKTAready flow paths and ReadyToProcess™ columns.

ÄKTAready is designed for process development, process scale-up, and small scale production.

ÄKTAready is controlled by UNICORN software version 5.11 or higher.

Symbols and typography

Menu commands, the names of dialogue boxes, windows and option buttons are written in a ***bold, italic*** typeface. Menu commands are written with the menu name and the command separated by a colon. For example, ***File:Open*** refers to the ***Open*** command in the ***File*** menu.

Names of hardware components relevant for user interaction, such as physical buttons, signs and indicators on the system cabinet, are written with bold typeface, e.g. **AIR VENT** button.

Emphasized words, as well as named references to other sections or documents are written with *italic* typeface.

Warning symbols

WARNING! The WARNING symbol and notice highlight instructions that must be followed to avoid personal injury. Do not proceed until all stated conditions are clearly understood and met.

Caution notices

CAUTION! The CAUTION notice highlights instructions that must be followed to avoid damage to the product or other equipment. Do not proceed until all stated conditions are met and clearly understood.

Notes

Note: A Note is used to indicate information that is important for trouble-free and optimal use of the product.

Associated documentation

ÄKTAready *User Manual* describes the operation of ÄKTAready. The user manual provides instructions for preparing the system and performing a run using UNICORN control system. The manual furthermore contains technical information, and instructions for troubleshooting and user maintenance.

ÄKTAready *Installation Guide* describes installation of the ÄKTAready system. The installation guide is primarily intended for service personnel authorized by GE Healthcare.

UNICORN control system is described in three manuals:

- *Getting Started*
- *User Reference Manual* (2 vol.)
- *Administration and Technical Manual*

WARNING! Read these safety instructions and all relevant user documentation before installing or using ÄKTAready.

WARNING! Do not operate ÄKTAready in any other way than described in the ÄKTAready and UNICORN manuals.

A list of associated documentation is found in an appendix in ÄKTAready *User Manual*.

1.2 General safety precautions

General

- Read the user manuals before using ÄKTAready.
- Any equipment connected to the system should meet the requirements of the IEC 61010 and local adaptations EN/UL. Within EU, connected equipment must be CE-labelled.
- Do not operate ÄKTAready hardware or UNICORN control system in any other way than described in ÄKTAready and UNICORN user manuals.

WARNING! Operation and user maintenance of ÄKTAready should be performed by properly trained personnel only.

Personal safety

To ensure personal safety during operation always use protective glasses and personal protective equipment appropriate for the current application. Personal protective equipment and protective clothing should be used according to local regulations and recommendations.

WARNING! High pressure. The ÄKTAready system operates under high pressure. Wear protective glasses at all times.

WARNING! Heavy object. The system weighs 230 kg. Use suitable lifting equipment and protective equipment when lifting the system. Protective footwear is required. All lifting and moving must be performed in accordance with local regulations.

Installation requirements

The system and the software should be installed and prepared by personnel authorized by GE Healthcare.

The ÄKTAready system is designed for indoor use only. In order to minimize any safety risks, and to obtain optimal function from the system it is important to pay

close attention to the environment in which the system is installed. The following conditions should be fulfilled:

- Minimal dust
- Placement on a level floor
- Avoid corrosive gas
- Avoid direct sunlight
- Avoid strong magnetic or electric fields
- Avoid vibration
- Ambient temperature between +2°C and +30°C
- Relative humidity 20%-95%, non-condensing

WARNING! Service, installation, and maintenance of components inside the system cabinet should be performed only by personnel authorized by GE Healthcare.

WARNING! ÄKTAready is not designed for use in an environment where explosion-proof equipment is required. The system does not fulfill the requirements of the ATEX Directive.

WARNING! Disconnect power. To prevent equipment damage, always disconnect power from the ÄKTAready system before an instrument module is removed or installed, or a cable is connected or disconnected.

See *ÄKTAready Installation Guide* for more information about installation of ÄKTAready.

Electricity

WARNING! No serviceable parts inside. Electrical shock hazard. All repairs should be done by service personnel authorized by GE Healthcare. Do not open any covers or replace parts unless specifically stated in the user documentation.

WARNING! Disconnect power. To prevent equipment damage, always disconnect power from the ÄKTAready system before an instrument module is removed or installed, or a cable is connected or disconnected.

Refer to *ÄKTAready Installation Guide* for instructions concerning configuration of mains power. The live and neutral cable conductors are distinguished by numbers, and protective ground by color:

Live — Black wire marked "1"

Neutral — Black wire marked "2"

Protective ground — Green/Yellow wire. Connector marked with symbol for earth connection.

Ground Fault Circuit Interruptors intended for protection of the operator are not available as an installation option from GE Healthcare. However, if ground fault protection for the system is desired, a Ground Fault Circuit Interruptor with a sensing threshold of ≥10 mA may be installed.

WARNING! Protective ground. ÄKTAready must always be connected to a grounded power outlet.

WARNING! Supply voltage. Before connecting the power cord, make sure that the supply voltage at the wall outlet corresponds to the marking on the instrument.

WARNING! High voltage. The mains cable should be connected by authorized service personnel. Faulty connection might result in live system parts that can give lethal electric shocks.

Lifting and moving

The ÄKTAready system is equipped with wheels and should normally not be lifted. See *ÄKTAready Installation Guide* for detailed information about lifting points, lifting equipment, etc.

Moving the system requires that the wheels are unlocked (see *ÄKTAready Installation Guide*).

WARNING! Heavy object. The system weighs 230 kg. Use suitable lifting equipment and protective equipment when lifting the system. Protective footwear is required.

WARNING! The wheels of the system should be locked during normal use. The wheels should be unlocked only when moving the unit.

WARNING! Moving the system on a sloping surface requires at least two persons.

WARNING! Risk of squeeze injury. Do not get caught between the moving system cabinet and other objects.

WARNING! Do not attempt to lift the system by the handle on the left side of the system cabinet. The handle is for manoeuvring the cabinet on the floor, not for lifting.

Avoid lifting heavy containers and columns. Use suitable lifting equipment and trolleys. Heavy columns are best transported and positioned using the column trolleys designed for the system (ordering information in appendix in *ÄKTAready User Manual*).

Compressed air

It is important, for both personal safety and safe operation of the system, that correct pressure and quality of compressed air is used. The basic requirements are:

- Oil- and particle-free

- -30°C dew point
- Working pressure 5.5 - 7 bar
- 50 Nl/m (normal liter per minute)

WARNING! Check that the Pressure Control Regulator for the system air supply is set to the pressure stated in the specifications (see ÄKTAready *User Manual*).

WARNING! Ensure that correct air pressure is always maintained. Too high or too low air pressure may be hazardous and may cause erroneous results and leakage.

1.3 Safety precautions during operation

General

This section covers possible hazards to operators of ÄKTAready systems in day-to-day work. Precautions when operating the equipment are primarily associated with high pressure, chemicals and mechanical components.

It is strongly recommended that the installation wizards provided with the system are used when installing new flow kits and columns. See ÄKTAready *User Manual* for instructions on how to open the wizards, and for a detailed description of the different steps included.

High pressure

During operation, the liquid in the system is under high pressure. The part of the flow path between pump and column may reach a maximum pressure of 5 bar. Always use ÄKTAready flow kits and ReadyToProcess columns, or other columns designed to withstand the pressure.

Before starting a run, make sure that:

- all inlets and outlets are properly assigned
- all connections are tightened
- there are no kinks or blockages anywhere in the flow path

WARNING! Use *only* ÄKTAready flow kits, supplied by GE Healthcare (ordering information in appendix in *ÄKTAready User Manual*).

WARNING! Over-pressure. Use columns that withstand expected pressures. If not, the columns might rupture, resulting in injury. Preferably use ReadyToProcess columns from GE Healthcare.

WARNING! Over-pressure. Before connecting the column, check that it is not damaged or otherwise defective. Damaged or defective columns might leak or burst.

WARNING! Over-pressure. Never block an assigned outlet tubing with, for instance, stop plugs, since this will create over-pressure and might result in injury.

WARNING! Over-pressure. The flow rate may under no circumstances exceed the specified column maximum flow rate. Excessive flow may affect the packed medium, causing the pressure to exceed the specified column maximum pressure. Excessive pressure may also damage the flow kit.

If excessive pressure is detected and the air trap is in line, press the **AIR VENT** button on the system cabinet to reduce the pressure.

If excessive pressure is detected when the air trap is ***bypassed***, take the following steps:

1 In UNICORN, set ***Manual Flow*** to 0, and set the airtrap in line.

2 Press **CONTINUE** (in UNICORN, or on the system cabinet).

3 Press the **AIR VENT** button on the system cabinet.

The flow path is depressurized through the air trap tubing.

CAUTION! The end of the air trap tubing should be directed away from the operator (preferably, it should be connected to a waste hose).

Chemicals

WARNING! Hazardous chemicals. When using hazardous chemicals, all suitable protective measures, such as wearing protective glasses, must be taken. Work with hazardous chemicals should furthermore be done in accordance with local regulations and recommendations. For a list of recommended chemicals, see appendix in ÄKTAready *User Manual*.

WARNING! Hazardous chemicals. When using hazardous chemicals, ensure that the entire flow path has been flushed thoroughly with distilled water before service and maintenance, and before dismounting of flow kits.

WARNING! Corrosive chemicals. NaOH is corrosive and therefore dangerous to health. Avoid spillage. Wear protective glasses and required protective clothing.

WARNING! Never leave a flow kit containing aggressive liquids mounted on the system for longer time periods. Either dispose of the flow path, or rinse it with water or suitable solution.

WARNING! ÄKTAready is not designed for use with flammable liquids or in potentially explosive environments. ÄKTAready does not fulfill the requirements of the ATEX Directive.

For a list of recommended liquids see appendix in *ÄKTAready User Manual*.

Mechanical components

Pinch valves

ÄKTAready system cabinet is equipped with pinch valves with tubing locks that are manually opened and closed when a new flow kit is mounted. When in operation, the pinch valves exert high mechanical force.

Although the valves are equipped with a lock with a protective plate there is still a risk of pinch injury when changing flow kit, or in case of air pressure failure. Warning labels indicate potential risk of pinch injury.

WARNING! Never put fingers or any objects other than the intended tubing in the pinch valve opening.

WARNING! Ensure that clothing or other equipment does not get caught in the pinch valves.

Pump

The peristaltic pump will only function with its lid securely fastened (see *ÄKTAready User Manual*). However, with the lid properly mounted there is a small opening next to the pump tubing where items could get stuck between the lid and the pump rollers.

The exterior surfaces of the pump may get hot during operation. After operation, allow time for the pump to cool down before touching it.

WARNING! Never touch the pump or pump lid while the pump is running.

Other precautions

WARNING! Only products recommended by GE Healthcare should be used with ÄKTAready. Use of non-authorized products may be hazardous, cause damage to the system, and/or have negative effects on performance.

WARNING! It is recommended that personnel working near ÄKTAready on a daily basis wear ear protection. High flow rates combined with high pressure can cause noise up to 75 dB(A).

CAUTION! Always make sure that the chromatography media, columns and system components are compatible with sodium hydroxide at the concentration, time, and temperatures used.

CAUTION! Do not allow solutions containing dissolved salts, proteins or other solid solutes to dry out in the UV cell. Do not allow particles to enter the cell as damage to the cell might occur.

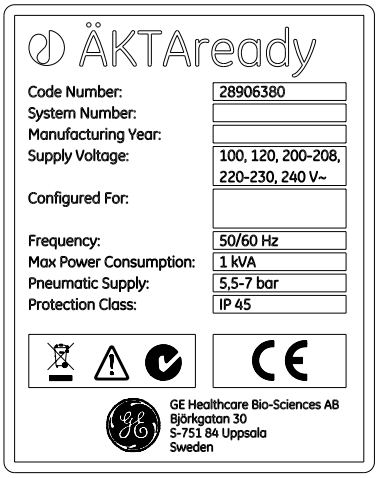
CAUTION! Excessive temperatures may damage the equipment. Do not run the system at higher temperatures than the specified maximum operation temperature (30°C).

1.4 Labels and indicators

System label

The system label is located on the right side of the leg support of the system cabinet (arrow in figure).

The **Code number** in the system label identifies the system as being an ÄKTAready system while the **Serial number** identifies the (unique) system installation.



The **Supply voltage** field gives the voltage alternatives for ÄKTAready. The voltage that the system is currently configured for is shown in the **Configured for** field. The configured voltage is assigned during installation. **Frequency** is the AC frequency of the power supply, and **Max Power Consumption** shows the maximum effect.

The **Pneumatic Supply** field shows the pressure range required for the compressed air supply. The **Protection class** is the electrical appliances protection classification according to international standard IEC 60529.

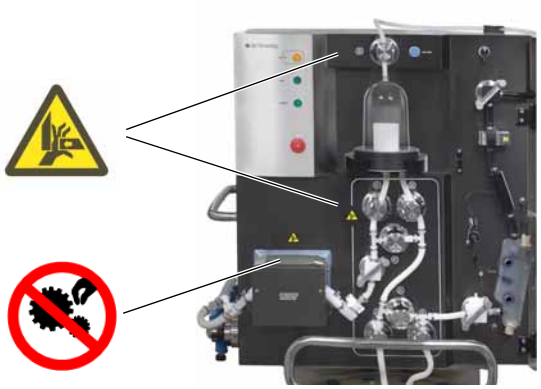
The symbols in the system label are:

Label	Description
	This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of equipment.

	WARNING! Read the user documentation before using the system. Do not open any covers or replace parts unless specifically stated in the user documentation.
	This system complies with the requirements for electromagnetic compliance (EMC) in Australia and New Zealand.
	This system meets all the essential requirements of applicable EU directives.

Safety labels

Safety labels are located on the front of the system cabinet as illustrated below. The labels warn the user of risk for personal injury.

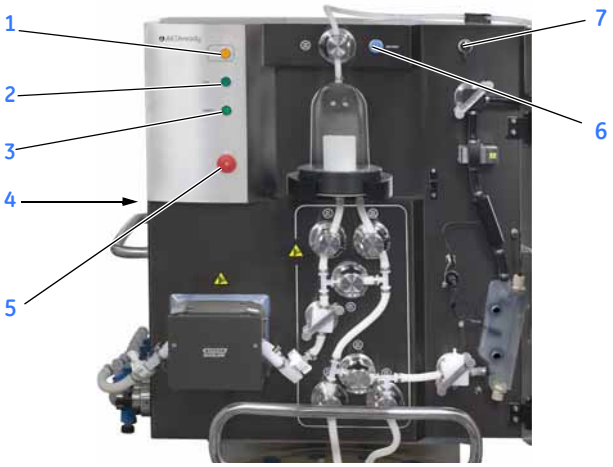


In the table below the safety labels are described. Make sure you fully understand the potential hazards indicated by the labels.

Label	Description
	WARNING! Pinch hazard. This sign is located next to pinch valves and close to the pump. Never put your fingers or any objects other than the intended tubing in the pinch valve openings. Ensure that clothing or other equipment does not get caught in the pinch valves.
	WARNING! Rotating rollers/cogwheels. This sign is located on the pump. Never touch the pump or pump lid while the pump is running. In case of emergency, press the emergency stop button (see next section). This immediately stops the pump.

Controls and indicators

The ÄKTAready system is equipped with the following indicators, switches and push-buttons:



A short description of each button and lamp is given in the following table. Text in bold typeface corresponds to the labels on the system cabinet. See ÄKTAready *User Manual* for detailed information about the function of buttons and indicator lamps.

No.	Component	Description
1	**PAUSE / CONTINUE** button and alarm indicator lamp	Press button to pause an ongoing process. Press again to continue. Lamp shows steady yellow light during pause. Flashing yellow light indicates UNICORN alarm.
2	**RUN** indicator lamp	Shows green light when system is running. No light when system is idle (between runs or during pause).
3	**POWER** indicator lamp	Shows flashing green light during initial communication connection, when power is switched on. Steady green light when power is on and communication with UNICORN software is established.
4	**Mains power** switch	System power switch, located on the left side of the unit.
5	Emergency stop button	Stops the pump and closes all inlet and outlet valves.

No.	Component	Description
6	**AIR VENT** — Air trap ventilation button	Button controlling air trap ventilation through valve **HV301**. Used for releasing excess air from air trap.
7	**Installation switch**	Used for releasing and engaging valves during flow kit and column installation. Three different positions: **FLOW KIT INSTALL**: Opens all valves. User can manually open/close valve locks. **RUN**: Engages all valves. User cannot open valve locks — valves are controlled by UNICORN. **COLUMN INSTALL**: Releases valves between column and air trap. Allows for removal of air in tubing between column and air trap. (The installation switch only works when the system is in its end state, not during run. If the switch is turned during a run, a warning will be issued. The switch will then have to be reset to **RUN** position in order to work.)

1.5 Emergency procedures

Emergency shutdown

In a situation where there is a risk of injury, switch off the ongoing run by pressing the emergency button on the front of the system cabinet. If required, also switch off the mains power supply.

The emergency switch immediately stops the pump motor and puts the system in pause mode.

WARNING! Pressing the emergency stop button does not automatically depressurize the flow path.

Restarting

To restart from pause mode, simply press the **PAUSE / ALARM** button. The system will continue the run with all settings intact.

Power failure routine

If electrical power to the system is lost, the ÄKTAready system pump stops and the valves revert to default positions.

WARNING! Power failure does not automatically depressurize the flow path.

If only the system is affected by the power failure and not the computer, UNICORN will display text saying that communication has been broken and that no data are recovered.

When power returns to normal, the system will be in End position (i.e., it will not resume the run).

A UPS (uninterrupted power supply) protects against temporary power failures by enabling the system to continue to operate for a limited time. A UPS is not included with the system. Contact your local GE Healthcare representative for more information about the options for your specific system.

1.6 Recycling

About recycling

When an ÄKTAready system is taken out of service, the different materials must be separated and recycled according to national and local environmental regulations. Contact your local GE representative for information about how to proceed.

Flow kits are disposed of according to local regulations regarding potentially dangerous waste.

For contact information for your local office, please visit
www.gelifesciences.com/contact

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